

REMARKS

Claims 36 and 61 are canceled without prejudice or disclaimer. Claims 1-32 were previously cancelled. Claims 49-52 and 54-57 are withdrawn from consideration. Claim 66 is added. Claim 66 is supported by the specification and claims as originally filed, including at page 6, line 2 to page 7, line 5. Claims 33-35, 37-48, 53, 58-60 and 62-66 are pending. Claims 33, 37-42, 45-48, 58, 59, and 62-65 are amended, as discussed below.

Claims 33, 58 and 59 are amended to recite that the variant has “above 80% homology to SEQ ID NO:1.” Support for this amendment is found in the specification at page 4, lines 21-22 and page 3, lines 8-line 21.

Claims 37-42, 46 and 62-65 are amended to recite the reference parent sequence (SEQ ID NO:1).

Claim 46 was determined to be a duplicate of claim 42, accordingly, claim 46 has been amended to depend from claim 41 instead of claim 33, so as to remove the duplicity.

Claim 45 is amended to add the temperature designation.

Claims 47 and 48 are amended to include a substitution for position A130.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance or in better condition for appeal to the Board of Patent Appeals. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. **Claim Objections**

Claims 33, 40-42, 45, 46, 58, 59 and 65 are objected to for various informalities, in particular, missing commas between the recited positions, a missing temperature symbol, and inconsistent reference to the reference sequence. Applicants respectfully submit that the objections have been resolved by the current amendment.

II. **The Rejection of Claims 47 and 48 under 35 U.S.C. 112 (New Matter)**

Claims 47 and 48 are rejected under 35 U.S.C. 112, as allegedly introducing new matter. The Examiner states that the specification does not support the variants EQ6+A14P+E47K+R51P+A130+E179Q and EQ6+A14P+N15D+E47K+R51P+A130+E179Q.

This rejection is rendered moot by the amendments to the claims.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 33-48, 53 and 58-65 under 35 U.S.C. 112 (Enablement)

Claims 33-48, 53 and 58-65 are rejected under 35 U.S.C. 112, as allegedly lacking enablement. The Examiner states that the claims lack enablement because, among other things, the claims include variants of parent cutinases having amino acid sequences that are about 56% homologous to SEQ ID NO:1.

In order to expedite prosecution, the claims recite that the variant cutinase has above 80% homology to SEQ ID NO:1. Applicants respectfully submit that the specification enables a skilled artisan to practice the cutinase variants defined by the present claims. The specification discloses many cutinases variants and examples of cutinase variants. See the specification at page 5 to page 7 and Example 2. Although the examples provided in the specification are generally directed towards a single reference sequence (SEQ ID NO:1), one skilled in the art would readily be able to produce with a reasonable expectation of success the cutinase variants recited in the claims, in particular, cutinase variants which have more than 80% homology to SEQ ID NO:1. The Examiner is correct that the amino acid sequence of a protein determines its structural and functional properties and what can be tolerated in the structure, and, in this regard, there is a high degree of predictability that a modification in one cutinase amino acid sequence will be tolerated in highly homologous cutinase amino acid sequences, including, those cutinases which share more than 80% homology to SEQ ID NO:1. That is, one skilled in the art would reasonably expect that the modifications recited in the claims and as exemplified in the specification would be applicable to homologous structures and one skilled in the art would have a very high degree of predictability of being able to make the recited cutinase variants.

The Examiner is also reminded that enablement is not precluded by the necessity of some experimentation, as the test for determining enablement is not whether *any* experimentation is required, but rather whether *undue* experimentation is required. As noted by the *In re Wands* court (*In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), the test for determining whether undue experimentation is required even permits a considerable amount of testing. Furthermore, even though the experimentation involved might be time consuming, it is the *nature* and not the *amount* of experimentation that is determinative of non-enablement. See *Hybritech v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986). The experimentation that would be required by the present invention is clearly not undue, but rather involves only routine testing, that is, to produce/screen the highly homologous cutinase variants recited in the claims.

Accordingly, Applicants respectfully submit that the specification provides sufficient guidance to enable one skilled in the art to make the claimed variants in a manner reasonably correlated with the scope of the claims and without undue experimentation.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,



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